

Claims

1. Solid pharmaceutical composition comprising
 - (a) an effective amount of ramipril and/or a pharmaceutical acceptable salt thereof and
 - (b) one or more pharmaceutically acceptable excipients,wherein the composition has a suitably low water content.
2. Composition according to claim 1, wherein the water content is less than about 5.5 weight-% measured by Karl-Fischer-analysis.
3. Composition according to claim 1, wherein the water content is less than about 4.5 weight-% measured by Karl-Fischer-analysis.
4. Composition according to any of the preceding claims, wherein ramipril and/or a pharmaceutical acceptable salt thereof is in form of pharmaceutically acceptable anhydrate, solvate and/or, hydrate and/or in crystalline and amorphous form.
5. Composition according to any of the preceding claims, wherein the pharmaceutical composition is a tablet.
6. Composition according to claim 5, wherein the tablet is suitably coated to generate a filmcoated tablet and/or a pill.
7. Composition according to claim 1 – 4, wherein the pharmaceutical composition is a capsule.
8. Composition according to claim 1 – 4, wherein the pharmaceutical composition is a sachet.
9. Composition according to any of the preceding claims, wherein the excipients have a suitably low water content.
10. Composition according to claim 9, wherein one of said excipients is microcrystalline cellulose.
11. Composition according to claim 1 - 9, wherein one of said excipients is Avicel PH 112.
12. Composition according to claim 9, wherein one of said excipients is starch.
13. Composition according to claim 1 - 9, wherein one of said excipients is Starch 1500 LM.
14. Composition according to claim 9, wherein one of said excipients is silicon dioxide.
15. Composition according to claim 1 - 9, wherein one of said excipients is Syloid AL-1 FP.
16. Composition according to claim 9, wherein one of said excipients is calcium hydrogen phosphate.

17. Composition according to claim 1 - 9, wherein one of said excipients is Dicafos A or A Tab or Anhydrous Emcompress.
18. Composition according to claim 9, wherein one of said excipients is lactose.
19. Composition according to claim 1 - 9, wherein one of said excipients is Pharmatose DCL 21.
20. Composition according to claim 9, wherein one of said excipients is mannitol.
21. Composition according to claim 1 - 9, wherein one of said excipients is Perlitol.
22. Composition according to claim 9, wherein one of said excipients is calcium sulphate.
23. Composition according to claim 1 - 9, wherein one of said excipients is Destab or Drierite.
24. Composition according to any of the preceding claims where one or more excipients are dried prior to use or throughout the manufacturing process to achieve the required level of water content.
25. Process for the preparation of a composition according to any of the preceding claims, wherein environmental conditions during manufacture are maintained at a relative humidity equal or less than 35% at ambient temperature.
26. Process for the preparation of a composition according to claim 1 - 23, wherein environmental conditions during manufacture are maintained at a relative humidity equal or less than 35% at equal or less than 30° C.
27. Process according to any of the preceding claims, wherein the pharmaceutical composition is packaged into a packaging material suitably tight against penetration of humidity.
28. Process according to claim 27, wherein the packaging material is a container including lid composed of polyethylene and/or polypropylene and/or glass.
29. Process according to claim 27, wherein the packaging material is a strip or blister pack composed of aluminium which might be suitably coated or high density polyethylene.
30. Package comprising a composition according to claims 1 - 23 packaged with packaging material suitably tight against penetration of humidity.
31. Package according to claim 30, wherein the packaging material is a container including lid composed of polyethylene and/or polypropylene and/or glass.
32. Package according to claim 30, wherein the packaging material is a strip or blister pack composed of aluminium which might be suitably coated or high density polyethylene.